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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,969	12/17/2001	John M. Irving	084/002	6623

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GERON CORPORATION
230 CONSTITUTION DRIVE
MENLO PARK, CA 94025

EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,969

Applicant(s)

IRVING ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to a replication –conditional adenovirus, classified in class 424, subclass 233.1.
- II. Claim 12, drawn to a method of selecting an adenovirus with specific features, classified in class 435, subclass 5.
- III. Claims 13 and 15, drawn to a method of killing a lung cancer cell, classified in class 424, subclass 277.1.
- IV. Claims 13 and 15, drawn to a method of killing a pancreatic cancer cell, classified in class 424, subclass 277.1.
- V. Claims 13 and 15, drawn to a method of killing a medulloblastoma cancer cell, classified in class 424, subclass 277.1.
- VI. Claims 13 and 15, drawn to a method of killing a cervical carcinoma cancer cell, classified in class 424, subclass 277.1.
- VII. Claims 13 and 15, drawn to a method of killing a fibrosarcoma cancer cell, classified in class 424, subclass 277.1.
- VIII. Claims 13 and 15, drawn to a method of killing a osteosarcoma cancer cell, classified in class 424, subclass 277.1.
- IX. Claim 14, drawn to a method of killing a cell expressing telomerase reverse transcriptase, classified in class 536, subclass 24.1.

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For the invention of groups I above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects groups I, election is further required for one of inventions (A)-(E).

- (A). Y-box transactivator, YB-1.
- (B). immediate early gene of CMV, CMV IE1
- (C). immediate early gene of CMV, CMV IE2
- (D). oncogenes of human papillomavirus, HPV E6
- (E). oncogenes of human papillomavirus, HPV E7

For the invention of group I above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects group I, election is further required for one of inventions (F)-(T).

- (F). tissue specific promoter: promoter for albumin.
- (G). tissue specific promoter: alpha-fetoprotein
- (H). tissue specific promoter: promoter for prostate-specific antigen (PSA).
- (I). tissue specific promoter: mitochondrail creatine kinase (MCK).
- (J). tissue specific promoter: myelin basic protein (MB).
- (K). tissue specific promoter: glail fibrillary acidic protein (GFAP).
- (L). tissue specific promoter: neuron specific enolase.
- (M). tumor specific promoter: telomerase reverse transcriptase (TERT), SEQ ID NO: 1
- (N). tumor specific promoter: cacinoembryonic antigen (CEA)
- (O). tumor specific promoter: hypoxia responsive element.
- (P). tumor specific promoter: Grp78.
- (Q). tumor specific promoter: L-plastin
- (R). tumor specific promoter: hexokinase II

The inventions are distinct, each from the other because of the following reasons:

Group I is drawn to a composition which differs from groups II-IX which are drawn to methods. Group I comprises a recombinant virus, which has specific functions. Group II is drawn to a method of selecting a virus with specific function. Groups III-IX are drawn to

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methods of killing cells and each method is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be the same. The type of cell destined to be killed is different for each method therefore the method that is applicable for one type of cells will not be applicable for another cell type as each cell will require a different virus construct. Though there may be overlap between these methods in question for groups III-IX, each utilizes different materials and therefore the outcome is expected to be different.

Inventions (A)-(E) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polynucleotides. Therefore, where structural identity is required, such as for hybridization, expression or activity, the different sequences have different effects.

Inventions (F)-(R) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polynucleotides. Therefore, where structural identity is required, such as for hybridization, expression or activity, the different sequences have different effects.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

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used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of group I can function as an antigen, which is a materially different process than measuring the competency of the viral construct. The construct will be an antigen regardless of whether it is capable of functions in the claimed process.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the groups are not required for another of the groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Ulrike Winkler, Ph.D.

1/24/03